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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/893,759 07/11/97 SAITOH

K 1587-0024-0

EXAMINER
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022850 HM22/0322  
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ART UNIT	PAPER NUMBER

1641  
DATE MAILED:

*25*  
03/22/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trad marks**

# Advisory Action

Application No.  
**08/893,759**

Applicant(s)  
**Saitoh et al**

Examiner  
**Chris Chin**

Group Art Unit  
**1641**



## THE PERIOD FOR RESPONSE: [check only a) or b)]

- a) ☒ expires 3 months from the mailing date of the final rejection.
- b) ☐ expires either three months from the mailing date of the final rejection, or on the mailing date of this Advisory Action, whichever is later. In no event, however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

- ☐ Appellant's Brief is due two months from the date of the Notice of Appeal filed on \_\_\_\_\_ (or within any period for response set forth above, whichever is later). See 37 CFR 1.191(d) and 37 CFR 1.192(a).

Applicant's response to the final rejection, filed on Mar 6, 1901 has been considered with the following effect, but is NOT deemed to place the application in condition for allowance:

- ☐ The proposed amendment(s):
- ☐ will be entered upon filing of a Notice of Appeal and an Appeal Brief.
  - ☐ will not be entered because:
    - ☐ they raise new issues that would require further consideration and/or search. (See note below).
    - ☐ they raise the issue of new matter. (See note below).
    - ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.
    - ☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

- ☐ Applicant's response has overcome the following rejection(s):

\_\_\_\_\_  
\_\_\_\_\_

- ☐ Newly proposed or amended claim's \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claims.
- ☒ The affidavit, exhibit or request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See attachment.

- ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

- ☒ For purposes of Appeal, the status of the claims is as follows (see attached written explanation, if any):

Claims allowed: None

Claims objected to: None

Claims rejected: 7-34

- ☐ The proposed drawing correction filed on \_\_\_\_\_ ☐ has ☐ has not been approved by the Examiner.
- ☐ Note the attached Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_.
- ☐ Other

Art Unit: 1641

## **DETAILED ACTION**

### ***Response to Amendment***

1. In response to the 112 2nd paragraph rejection of claims 7 and 21, Applicants argue that the meaning of the recitation that one of the antibodies “does not have strict specificity for the antigen” would be readily understood by one skilled in the art.

Applicant’s argument has been considered but is not convincing. The phrase being argued by Applicants is not considered a correlation step. Claims 7 and 21 require an additional step that relates the detected agglutinate to the presence of antigen as set forth in the preamble of claims 7 and 21.

In response to the art rejections Applicants have provided comments by one of the inventors, Mr. Saitoh, which explain in detail the reasons why the claimed invention is so advantageous that the same level of performance is not provided by other classical techniques.

The comments from Mr. Saitoh have been duly noted but they cannot be relied upon to overcome the art rejections because they have been presented as opinions which carry no weight in determining patentability. Mr. Saitoh’s comments should have been presented in the form of a Rule 1.132 declaration along with experimental evidence to support the assertions of superior levels of performance over prior art methods.

Art Unit: 1641

In response to the Strahilevitz and EP '285 references, Applicants argue that Strahilevitz and the EP '285 references fail to disclose using one antibody having high specificity for the antigen while the other [second] antibody does not have strict specificity for the antigen.

Applicant's argument has been considered but is not convincing. The limitation of having an antibody that does not have strict specificity for the antigen is interpreted as an antibody that (1) can bind to the antigen or (2) can bind to something else. The fact that Strahilevitz and EP '285 teach a second antibody that binds to the antigen is sufficient to meet to the first part of how this limitation is being interpreted and thus still anticipates the claimed method.

In response to the Cragle et al reference, Applicants note deficiencies in the method of Cragle et al. However, since Applicant's arguments fail to address the combined teachings of Cragle et al in view of Strahilevitz and EP '285, Applicant's arguments are not convincing.

### ***Conclusion***

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chris Chin whose telephone number is (703) 308-3991. The examiner can normally be reached on Monday-Thursday from 9:30 am to 7:00 pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.


Application/Control Number: 08/893,759

Page 4

Art Unit: 1641

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

cchin/cc  
March 21, 2001

A handwritten signature in cursive script, reading "Christopher L. Chin".

CHRISTOPHER L. CHIN  
PRIMARY EXAMINER  
GROUP 1800-1641